



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 10/598,112 | 03/05/2007 | Craig A. Judy | 3488/105 | 1150 |
| 32665 | 7590 | 06/11/2009 | | |
| LESLIE MEYER-LEON, ESQ. | | | EXAMINER | |
| Bromberg & Sunstein LLP | | | PURDY, KYLE A | |
| 125 Summer Street | | | | |
| 11th Floor | | | ART UNIT | PAPER NUMBER |
| Boston, MA 02110-1618 | | | 1611 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 06/11/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|------------------------------------|
| Office Action Summary | Application No. 10/598,112 | Applicant(s) JUDY ET AL. |
| | Examiner Kyle Purdy | Art Unit 1611 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 January 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-27 is/are pending in the application.
 4a) Of the above claim(s) 15-27 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-14 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1448)
 Paper No(s)/Mail Date 1 page (05/13/2009)

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/02/2009 has been entered.

Status of Application

2. The Examiner is not in receipt of any amendments or arguments filed subsequent to the filed RCE. The Examiner will address Applicant in terms of the arguments made on 12/01/2008 and the content of the interview conducted on 01/09/2009.

3. Claims 1-14 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

4. Applicants arguments filed 12/01/2008 regarding the rejection of claims 1-5 and 10 made by the Examiner under 35 USC 102(b) Dandiker et al. (US 5425950) have been fully considered and they are found persuasive. This rejection is withdrawn as Dandiker does not disclose Applicants rapid release mantle free of sumatriptan.

5. Applicants arguments filed 12/01/2008 regarding the rejection of claims 1-5 and 10-14 made by the Examiner under 35 USC 103(a) Dandiker in view of Lerner et al. (US 2004/0052843) have been fully considered and they are found persuasive. This rejection is withdrawn as Dandiker does not disclose Applicants rapid release mantle free of sumatriptan.

6. Applicants arguments filed 12/01/2008 regarding the rejection of claims 1 and 5-9 made by the Examiner under 35 USC 103(a) Dandiker in view of Lieberman et al. (Pharma. Dosage Forms, 1990) have been fully considered and they are found persuasive. This rejection is withdrawn as Dandiker does not disclose Applicants rapid release mantle free of sumatriptan.

New Rejections
Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al. (US 5425950; of record) in view of Holt et al. (US 6740341; filed 11/24/1999) and meds.com (<http://www.meds.com/conrad/aash/guterman.html>, Sept 1997).**

10. Dandiker is drawn to a controlled pharmaceutical composition comprising a core and an outer coating(s). The core is to comprise the anti-migraine agent, sumatriptan. The core is to

possess surrounding layers which may be active-agent containing rapid release layer (see column 3, line 35-37). The core composition comprises in addition to sumatriptan, a filler (microcrystalline cellulose), a binder (polyvinylpyrrolidone), a disintegrant (microcrystalline cellulose) and a lubricant (sodium stearyl fumerate) (see Example 10). For clarity, Example 10 is pasted below:

Core and Coating

- A) Drug: Sumatriptan, 50% w/w;
- B) Filler: Microcrystalline cellulose, 23% w/w;
- C) Binder: Polyvinylpyrrolidone, 2% w/w;
- D) Disintegrant: Microcrystalline cellulose, 23% w/w;
- E) Lubricant: sodium stearyl fumerate, 2% w/w;
- F) Adsorbent: not specifically disclosed, no specified w/w %; and
- G) Colorant: optional (see column 5, lines 65-68; see instant claim 6)

11. As can be seen above, the rapid release coating is to contain essentially the same excipients (see columns 5 and 6 and Examples 10; see instant claims 5). The tablet formulation of Example 10 contains 50 mg of sumatriptan (see column 14, lines 30-35; see instant claim 4) and the weight ratio of mantle to core is 1.3:1 as the core had a weight of 100 mg and the coating had a weight of 130 mg (230 mg – 100 = 130 mg; see column 14, lines 45-50; see instant claims 2-3). This corresponds to a weight ratio of mantle to core of 1.3:1. It's noted that rapid release requires that the layers dissolve completely within less than 10 minutes (see column 5, lines 15-18).

12. While Dandiker teaches a rapid release coating, the coating is required to possess an active agent which may or may not be sumatriptan.

13. Holt is directed to a taste masking rapid release coating system. Holt teaches a core containing a drug encased in a spacing layer and a taste masking layer which provide effective taste masking for in mouth disintegrable dosage forms containing highly objectionable tasting drugs. The taste mask coating is to be rapidly released. An exemplified class of drugs is anti-migraine actives (see column 3, line 65). Moreover, the composition may contain colorants or adsorbants.

14. Meds.com teaches that sumatriptan has a bitter and unpleasant taste (see page 2).

15. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Dandiker in view of Holt and Meds.com with a reasonable expectation for success in arriving at a tablet comprising a core containing sumatriptan and a rapid release mantle, free of sumatriptan, wherein the mantle entirely surrounds the core. Providing a coating around the core of Dandiker, wherein the coating is free of sumatriptan would have been obvious, especially in view of Holt. While Dandiker requires a drug to be present in the rapid release coating, Holt does not. In fact, Holt teaches that no drug is to be present in the outer taste mask coating. The taste mask coating is to hide the taste of the drugs bad taste. This would have been obvious especially in view of Meds.com which teaches that sumatriptan possess an unpleasant and bitter taste. . Thus, one would have been motivated to combine the teachings such that the resultant composition has a core comprising sumatriptan and a coating free of sumatriptan so that upon administration of the tablet, the user will not experience any of the unpleasant taste associated with sumatriptan consumption. With respect to

the requirement that the core and the mantle disintegrate over the same time period, this is also obvious. As the suggested modified coating would be substantially the same as the core, excluding the sumatriptan, one would reasonably expect that the disintegration properties of each layer would be essentially the same, if not identical. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.
17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/
Examiner, Art Unit 1611
May 27, 2009*

*/David J Blanchard/
Primary Examiner, Art Unit 1643*